

## **REMARKS**

Claims 36-41 and 68-76 are pending in the application. Claims 1-35 and 42-67 have been cancelled by previous amendments. Claims 36 and 72 have been amended as explained below.

Applicants thank the Examiner for her consideration of Applicants' previous arguments and the withdrawal of all previous rejections.

### **Information Disclosure Statements**

Applicants respectfully advise the Examiner that Applicants filed a Third Supplemental Information Disclosure Statement on June 4, 2004 (shown on the PTO PAIR system as having a Mail Room Date of June 7, 2004). This IDS included the English language translation of German Patent Application No. DT 23 43 987. Applicants sent the original, German language reference with the IDS filed April 28, 2004. Applicants request that the Examiner initial and return a copy of the PTO-1449 that is part of Applicants' Third Supplemental IDS filed June 4, 2004 to reflect the Examiner's review of the translation.

### **Certified Translation of Priority Document**

Applicants would like to bring to the Examiner's attention the certified translation of the priority document that Applicants filed on June 4, 2004. In the Office Action, the Examiner suggests that this translation has not been filed (see page 4, ¶ 8). Applicants request that the Examiner confirm the receipt of the translation.

### **Rejections Pursuant to 35 U.S.C. §112**

Claims 69 and 72-76 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite with respect to the language "capable of transporting" and "capable of binding." As the Examiner has suggested, Applicants have amended these claims to recite "which transports" and "which binds." Applicants make this amendment solely to expedite prosecution and do not intend the amendment to limit the claims in any manner.

## Rejections Pursuant to 35 U.S.C. § 102

Claims 36–41 and 68–76 stand rejected pursuant to 35 U.S.C. § 102 as anticipated by Zaun et al. (U.S. Patent No. 5,415,839)(hereinafter “Zaun et al.”). Applicants respectfully disagree with the rejection because Zaun et al. does not teach each and every limitation of independent claims 36, 68 and 72.

For example, Zaun et al. does not teach “a binding space for purifying the nucleic acids by immobilizing the nucleic acids and separating impurities” as recited in claim 36. The Examiner incorrectly cites to column 8, lines 20-32 of Zaun et al., which describes microparticle beads in the bottom of a reaction chamber, as teaching the claim limitation. This disclosure, however, does not describe a binding space for purifying nucleic acids. Zaun describes that these particles are inert, and that the function of these beads are as nucleation sites for vaporization to begin at or near the bottom of the sample. (column 8, lines 15-17 and 25-32). Nothing in this disclosure teaches a binding space for purifying nucleic acids. In fact, the entire disclosure of Zaun et al. assumes that the nucleic acids are already purified prior to their addition into the reaction chamber. Nowhere does Zaun et al. teach that the apparatus can purify nucleic acids. (See, column 31, line 21 through column 33, line 31 which discusses amplification, but not purification of nucleic acids; *see also*, Examples 5 and 11 (columns 38 and 40) describing “Reaction Sample Preparation[s]” that fail to describe purification of nucleic acids). Moreover, even if the microparticle beads were to bind nucleic acids as the Examiner suggests, Zaun et al. does not describe that these beads are transported to the detection chamber. Therefore, there is no description of how the nucleic acids can be detected if they are bound to the beads.

In addition, Zaun et al. fails to teach that “at least a part of the amplification space is identical to a part of the binding space” as recited in claim 36. The Examiner cites to column 7, lines 31-50 and column 8, lines 6-32 for this teaching. As explained immediately above, however, Zaun et al. does not teach a binding space for purifying nucleic acids. Therefore, there can be no teaching of a binding space that is identical to an amplification space as recited in claim 36. Accordingly, because Zaun et al. does not

teach each and every limitation of claim 36, Zaun et al. does not anticipate claim 36 under 35 U.S.C. § 102.

Similarly, with regard to claim 72, Zaun et al. does not teach a space comprising a surface which binds nucleic acids, and reagents for amplifying and detecting the nucleic acids that become bound to the surface. Even if the Examiner were accurate that the particles in the bottom of the reaction chamber in Zaun et al. are a surface for binding nucleic acids (which, as explained above is not accurate), there is no disclosure in Zaun et al. that explains how the amplified nucleic acids would be transferred to the detection space instead of binding to the particles. Furthermore, even assuming that the particles could be transferred, there is no disclosure in Zaun et al. that explains how the nucleic acids bound to those particles could be detected in the detection space. The absence of such disclosure shows that the microparticle beads described in Zaun et al. are not a binding space as recited in claim 72. Because Zaun et al. does not teach each and every limitation of claim 72, Zaun et al. does not anticipate claim 72 under 35 U.S.C. § 102.

With regard to independent claim 68, Zaun et al. does not teach a “capillary reaction vessel surrounded by a single heatable metal layer that is coated on the reaction vessel” as recited in claim 68. The Examiner cites to column 12, lines 5-40 of Zaun, et al. as teaching this limitation. This disclosure, however, describes a one or two heating rings that are not a single heatable metal layer coated on the reaction vessel. In fact, this disclosure teaches that the heating rings are part of a completely separate instrument into which the reaction vessel is placed. None of the disclosure teaches a single, metal layer that surrounds the reaction vessel and is coated on the reaction vessel. Because Zaun et al. does not teach each and every limitation of claim 68, Zaun et al. does not anticipate claim 68 under 35 U.S.C. § 102.

In the foregoing, Applicants have explained why Zaun et al. does not teach each and every limitation of independent claims 36, 68 and 72. Accordingly, Zaun et al. does not anticipate these claims under 35 U.S.C. § 102. Also, because each of the dependent claims includes all of the limitations of the independent claim from which it depends, the dependent claims are not anticipated. Accordingly, no further analysis is necessary for

the dependent claims. Applicants, however, will address some of the dependent claims since the Examiner fails to show how Zaun et al. teach many of the limitations recited in the dependent claims. Applicants decision not to address every dependent claim should not be considered an agreement with the Examiner arguments regarding the claims that Applicants do not address.

For example, with regard to claims 37 and 73, the Examiner asserts that column 7, lines 17-26 and 53-57 of Zaun et al. teach an apparatus comprising reagents for purifying nucleic acids as recited in claims 37 and 73. This disclosure, however, has nothing to do with purifying nucleic acids. To the extent the Examiner refers to the capture reagents that are present on support 60 in Zaun et al., these reagents only bind nucleic acids that have already been purified and amplified. There is no disclosure of reagents to purify nucleic acids so that they may then be amplified and detected. Accordingly, Zaun et al. does not teach the limitations of claims 37 and 73.

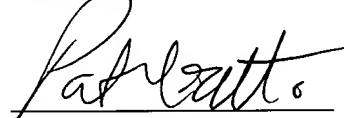
With regard to claim 38, the Examiner is incorrect in asserting that the disclosure of column 8, lines 34-41, and column 9, lines 40-67 teach a detection space comprising a part of at least one of the amplification space and the binding space. Contrary to the Examiner's conclusion, Zaun et al. clearly teaches that the reaction chamber and the detection chamber are separate and distinct, and connected only to transfer the amplified nucleic acids from the reaction chamber to the detection chamber. (*See*, column 11, line 17 – column 12, line 2). No part of the amplification reaction in Zaun et al. occurs in the detection chamber, and none of the detection occurs in the amplification chamber. In fact, the Examiner acknowledges that the chambers in Zaun et al. are separate, and only the open end of the reaction chamber connects to the detection chamber. Zaun et al. does not teach that the chambers comprise the same space, as recited in claim 38, simply because Zaun et al. describes that the open end of one chamber connects with the open end of another. Accordingly, Zaun et al. does not teach the limitation of dependent claim 38.

## CONCLUSION

With the above amendments and remarks, Applicants respectfully submit that the application is in condition for allowance. If Examiner is of the opinion that a telephone conference would expedite prosecution of the application, Examiner is encouraged to contact Applicants' undersigned representative.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Patrick G. Gattari", written over a horizontal line.

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